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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,920	09/23/2003	David W. Morris	20366-066001; PP23362.000	2631
7590 Lisa E. Alexander Sagres Discovery, Inc. c/o Chiron Corporation P.O. Box 8097 Emeryville, CA 94662-8097			EXAMINER HARRIS, ALANA M	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 02/03/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/669,920	Applicant(s) MORRIS ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61,71,72,74,77-79,81,85-89 and 91-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61,71,72,74,77-79,81, 85-89 and 91-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment and Arguments

1. Claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 are pending.
Claims 61, 71, 77-79, 81, 85 and 87-89 have been amended.
Claims 91-93 have been added.
Claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Grounds of Rejection

Claim Rejections - 35 USC § 112

3. The rejection of claims 87-89 and 93 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

New Grounds and Maintained Rejection

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1643

5. Claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants broadly claim methods of diagnosing breast cancer comprising detecting differential expression of complement receptor type 1 (CR1) gene in a patient sample, wherein evidence of differential expression is detected by measuring the level of an expression product of CR1 and wherein the expression product is a mRNA having a sequence of SEQ ID NO: 1320 and detecting duplexes with an hybridization assay. Applicants assert CR1 is a gene that encodes a single pass transmembrane glycoprotein that has the ability to bind key components of the complement cascade and can inhibit both the classical and alternative pathways, see Remarks, page 6. Zhang et al./ U.S. Patent Application Publication number US 2007/0099251 A1 (published May 3, 2007) has sequence 14579 that shares 97% with Applicants' SEQ ID NO: 1320 and is noted as a complement C3b/C4b receptor-like protein, see sequence alignment following the rejection. It is art known that the complement system comprises a multitude of proteins circulating in blood plasma, hence the complement system and its component exists in normal individuals as well as those that may have breast cancer. It is not clear whether or not one of ordinary

Art Unit: 1643

skill in the art can effectively and discriminately implement the claimed assay given the protein in the claimed invention exists naturally. It stands to reason that SEQ ID NO: 1320 would be detected in all patient samples, both cancerous and non-cancerous. The specification does not exemplify examples supporting that at the time of the claimed invention was made that Applicants were able to discriminately diagnose any cancers given CR1 ubiquitous nature. There needs to be some valid amount of direction or guidance, as well as presence or absence of working examples presented in the specification that would enable one skilled in the art to perform the method as presented in the recited claims. It appears that undue experimentation would be required of one skilled in the art to practice the instant claimed invention using the teachings of the specification. See *Exparte Forman*, 230 USPQ 546 BPAI, 1986. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

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RESULT 2
US-11-582-861-14579
; Sequence 14579, Application US/11582861
; Publication No. US20070099251A1
; GENERAL INFORMATION:
; APPLICANT: Zhang, Hui
; APPLICANT: Aebersold, Rudolf H.
; TITLE OF INVENTION: TISSUE- AND SERUM-DERIVED GLYCOPROTEINS
; TITLE OF INVENTION: AND METHODS OF THEIR USE
; FILE REFERENCE: 460092.404
; CURRENT APPLICATION NUMBER: US/11/582,861
; CURRENT FILING DATE: 2006-10-17
; PRIOR APPLICATION NUMBER: US 60/728,044
; PRIOR FILING DATE: 2005-10-17
; NUMBER OF SEQ ID NOS: 14918
; SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 14579
; LENGTH: 1793
; TYPE: DNA
; ORGANISM: Homo sapiens
US-11-582-861-14579
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Art Unit: 1643

Query Match 97.2%; Score 1495.4; DB 13; Length 1793;
Best Local Similarity 99.9%; Pred. No. 0;
Matches 1496; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

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Qy      34  ACTCAGAAGGGACTTCCCTGCTCGGCTGGCTTTTCGGTTTCTCTGCTCACCTCCGGATAAA 93
      |||
Db      1  ACTCAGAAGGGACTTCCCTGCTCGGCTGGCTTTTCGGTTTCTCTGCTCACCTCCGGATAAA 60

Qy     94  TCACGGGGTCTCCCGCGCCGCTCATGGCGCCTCCCGTCCGTCTCGAGCGTCCCTTTCCTT 153
      |||
Db     61  TCACGGGGTCTCCCGCGCCGCTCATGGCGCCTCCCGTCCGTCTCGAGCGTCCCTTTCCTT 120

Qy    154  CCCGGCGCTTTCCTGGGTTGCTTCTGGCGGCCCTGGTGTGCTGCTGTCTCCTTCTCCG 213
      |||
Db    121  CCCGGCGCTTTCCTGGGTTGCTTCTGGCGGCCCTGGTGTGCTGCTGTCTCCTTCTCCG 180

Qy    214  ATCAATGCAATGTCCCGGAATGGCTTCCATTTGCCAGGCCTACCAACCTAACTGATGACT 273
      |||
Db    181  ATCAATGCAATGTCCCGGAATGGCTTCCATTTGCCAGGCCTACCAACCTAACTGATGACT 240

Qy    274  TTGAGTTTCCCATTTGGGACATATCTGAACTATGAATGCCGCCCTGGTTATTCGGGAAGAC 333
      |||
Db    241  TTGAGTTTCCCATTTGGGACATATCTGAACTATGAATGCCGCCCTGGTTATTCGGGAAGAC 300

Qy    334  CGTTTTCTATCATCTGCCTAAAAAACTCAGTCTGGACAAGTGCTAAGGACAAGTGCAAAC 393
      |||
Db    301  CGTTTTCTATCATCTGCCTAAAAAACTCAGTCTGGACAAGTGCTAAGGACAAGTGCAAAC 360

Qy    394  GTAAATCATGTCGTAATCCTCCAGATCCTGTGAATGGCATGGCACATGTGATCAAAGACA 453
      |||
Db    361  GTAAATCATGTCGTAATCCTCCAGATCCTGTGAATGGCATGGCACATGTGATCAAAGACA 420

Qy    454  TCCAGTTCGGATCCCAAATTAATATTCTTGTCTAAAGGATACCGACTCATTTGGTTCCT 513
      |||
Db    421  TCCAGTTCAGATCCCAAATTAATATTCTTGTCTAAAGGATACCGACTCATTTGGTTCCT 480

Qy    514  CGTCTGCCACATGCATCATCTCAGGCAACACTGTCATTTGGGATAATAAAACACCTGTTT 573
      |||
Db    481  CGTCTGCCACATGCATCATCTCAGGCAACACTGTCATTTGGGATAATAAAACACCTGTTT 540

Qy    574  GTGACAGAAATTATTTGTGGGCTACCCCCACCATCGCCAATGGAGATTTCACTAGCATCA 633
      |||
Db    541  GTGACAGAAATTATTTGTGGGCTACCCCCACCATCGCCAATGGAGATTTCACTAGCATCA 600

Qy    634  GCAGAGAGTATTTTCACTATGGATCAGTGGTGACCTACCACTGCAATCTTGAAGCAGAG 693
      |||
Db    601  GCAGAGAGTATTTTCACTATGGATCAGTGGTGACCTACCACTGCAATCTTGAAGCAGAG 660

Qy    694  GGAAAAAGGTGTTTGTGGCTTGTGGGTGAGCCCTCCATATACTGCACCAGCAAAGATGATC 753
      |||
Db    661  GGAAAAAGGTGTTTGTGGCTTGTGGGTGAGCCCTCCATATACTGCACCAGCAAAGATGATC 720

Qy    754  AAGTGGGCATCTGGAGTGGCCAGCCCCCTCAGTGCATTATACCTAACAAATGCACGCCTC 813
      |||
Db    721  AAGTGGGCATCTGGAGTGGCCAGCCCCCTCAGTGCATTATACCTAACAAATGCACGCCTC 780

Qy    814  CAAATGTGGAAATGGAATATTGGTATCTGACAACAGAAGCTTATTTTCCTTAAATGAAG 873
      |||
Db    781  CAAATGTGGAAATGGAATATTGGTATCTGACAACAGAAGCTTATTTTCCTTAAATGAAG 840

Qy    874  TTGTGGAGTTTAGGTGTCAGCCTGGCTTTGGCATGAAAGGGCCCTCCCATGTGAAGTGCC 933
      |||
Db    841  TTGTGGAGTTTAGGTGTCAGCCTGGCTTTGGCATGAAAGGGCCCTCCCATGTGAAGTGCC 900

Qy    934  AGGCCCTGAACAAATGGGAGCCAGAGTTACCAAGCTGCTCCAGGGTATGTCAGCCACCTC 993
      |||
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Art Unit: 1643

Db 901 AGGCCCTGAACAAATGGGAGCCAGAGTTACCAAGCTGCTCCAGGGTATGTCAGCCACCTC 960

Qy 994 CAGATGTCCTGCATGCTGAGCGTACCCAAAGGGACAAGGACAACCTTTTCACCCGGGCAGG 1053
|||||

Db 961 CAGATGTCCTGCATGCTGAGCGTACCCAAAGGGACAAGGACAACCTTTTCACCCGGGCAGG 1020

Qy 1054 AAGTGTTCCTACAGCTGTGAGCCCCGGCTACGACCTCAGAGGATCTACGTATTTGCACTGCA 1113
|||||

Db 1021 AAGTGTTCCTACAGCTGTGAGCCCCGGCTACGACCTCAGAGGATCTACGTATTTGCACTGCA 1080

Qy 1114 CACCCCAGGGAGACTGGAGCCCTGCAGCCCCCAGATGTGAAGTGAAATCCTGTGATGACT 1173
|||||

Db 1081 CACCCCAGGGAGACTGGAGCCCTGCAGCCCCCAGATGTGAAGTGAAATCCTGTGATGACT 1140

Qy 1174 TCCTGGGCCAACTTCCTAATGGCCATGTGCTATTTCCACTTAATCTCCAGCTTGGAGCAA 1233
|||||

Db 1141 TCCTGGGCCAACTTCCTAATGGCCATGTGCTATTTCCACTTAATCTCCAGCTTGGAGCAA 1200

Qy 1234 AAGTGGATTTTGTGTTGTGATGAAGGATTTCAATTAAGGAGCAGCTCTGCTAGTTACTGTG 1293
|||||

Db 1201 AAGTGGATTTTGTGTTGTGATGAAGGATTTCAATTAAGGAGCAGCTCTGCTAGTTACTGTG 1260

Qy 1294 TTTTGGCTGGAATGAAAAGCCTTTGGAATAGCAGTGTTCCAGTGTGTGAACGTAAATCAT 1353
|||||

Db 1261 TTTTGGCTGGAATGAAAAGCCTTTGGAATAGCAGTGTTCCAGTGTGTGAACGTAAATCAT 1320

Qy 1354 GTGAAACTCCTCCAGTTCCAGTGAATGGCATGGTGCATGTGATCACAGACATCCATGTTG 1413
|||||

Db 1321 GTGAAACTCCTCCAGTTCCAGTGAATGGCATGGTGCATGTGATCACAGACATCCATGTTG 1380

Qy 1414 GATCCAGAATCAACTATTCTTGTACTACAGGGCACCGACTCATTGGTCACTCATCTGCTG 1473
|||||

Db 1381 GATCCAGAATCAACTATTCTTGTACTACAGGGCACCGACTCATTGGTCACTCATCTGCTG 1440

Qy 1474 AATGTATCCTCTCGGGCAATACTGCCCATTGGAGCATGAAGCCACCAATTTGTCAAC 1530
|||||

Db 1441 AATGTATCCTCTCGGGCAATACTGCCCATTGGAGCATGAAGCCACCAATTTGTCAAC 1497

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. The rejection of claims 61, 71, 72, 74, 77-79, 81, 85, 91 and 92 under 35 U.S.C. 102(b) as being anticipated by Qi et al. (Abstract from British Journal of Cancer 69(5): 903-910, 1994) is maintained.

Applicants assert cripto-1 (CR-1) referenced in the prior art is distinct from complement receptor type 1 (CR1) listed in the claims, see Remarks

Art Unit: 1643

submitted November 18, 2009, page 6. Applicants state Attachment A supports the claimed differences between CR-1 and CRI and consequently respectfully request removal of the instant rejection. These points of view and arguments have been carefully considered, but found unpersuasive.

Attachment A, a reference by Watanabe did not accompany Applicants' arguments. Applicants' assertions and statements are not found persuasive. Applicants' statements do not replace scientific facts and said statements should be corroborated by scientific evidence. For the reasons of record the rejection is maintained.

9. The rejection of claims 91 and 92 under 35 U.S.C. 102(b) as being anticipated by Saeki et al. (Cancer Research 52: 3467-3473, June 15, 1992) is maintained.

Applicants assert cripto-1 (CR-1) referenced in the prior art is distinct from complement receptor type 1 (CRI) listed in the claims, see Remarks submitted November 18, 2009, page 7. Applicants state Attachment A supports the claimed differences between CR-1 and CRI and consequently respectfully request removal of the instant rejection. These points of view and arguments have been carefully considered, but found unpersuasive.

Attachment A, a reference by Watanabe did not accompany Applicants' arguments. Applicants' assertions and statements are not found persuasive. Applicants' statements do not replace scientific facts and said statements

Art Unit: 1643

should be corroborated by scientific evidence. For the reasons of record the rejection is maintained.

10. The rejection of claims 61, 71, 72, 74, 77-79, 81, 85, 86, 91 and 92 under 35 U.S.C. 102(e) as being anticipated by Cassart/ U.S. Patent Application Publication number 2004/0054142 A1 (effective filing date August 4, 2003) is maintained.

Applicants assert cripto-1 (CR-1) referenced in the prior art is distinct from complement receptor type 1 (CRI) listed in the claims, see Remarks submitted November 18, 2009, page 7. Applicants state Attachment A supports the claimed differences between CR-1 and CRI and consequently respectfully request removal of the instant rejection. These points of view and arguments have been carefully considered, but found unpersuasive.

Attachment A, a reference by Watanabe did not accompany Applicants' arguments. Applicants' assertions and statements are not found persuasive. Applicants' statements do not replace scientific facts and said statements should be corroborated by scientific evidence. For the reasons of record the rejection is maintained.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The rejection of claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 under 35 U.S.C. 103(a) as being unpatentable over Qi et al. (Abstract from British Journal of Cancer 69(5): 903-910, 1994), and further in view of Cassart/ U.S. Patent Application Publication number 2004/0054142 A1 (effective filing date August 4, 2003) and Olsen/ U.S. Patent 6,852,506 B1 (filed April 11, 1997) is maintained.

Applicants assert cripto-1 (CR-1) referenced in the prior art is distinct from complement receptor type 1 (CRI) listed in the claims, see Remarks submitted November 18, 2009, page 7. Applicants state Attachment A supports the claimed differences between CR-1 and CRI and consequently respectfully request removal of the instant rejection. These points of view and arguments have been carefully considered, but found unpersuasive.

Attachment A, a reference by Watanabe did not accompany Applicants' arguments. Applicants' assertions and statements are not found persuasive. Applicants' statements do not replace scientific facts and said statements

Art Unit: 1643

should be corroborated by scientific evidence. For the reasons of record the rejection is maintained.

Double Patenting

13. The provisional rejection of claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42, 43, 44 and 49 of copending Application No. 10/573,332 (filed April 6, 2007) is maintained and made.

Applicants have renewed their request this rejection be held in abeyance until an indication of allowable subject matter is indicated, see page 8 of the Remarks submitted of November 18, 2009. This point of view has been carefully considered and the rejection is maintained for the reason within and set forth previously in the Action mailed November 19, 2007.

14 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a *flexible schedule*, however she can normally be reached Monday through Saturday between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-

Art Unit: 1643

0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
25 January 2010

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643